



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g1401d

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

June 18, 2001

Ref: 2001-DAL-WL- 28

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert S. Morrison
President and Chief Executive Officer
The Quaker Oats Company
321 North Clark Street
P.O. Box 9001
Chicago, Illinois 60604-9001

Dear Mr. Morrison:

An inspection of your food manufacturing facility, The Quaker Oats Company, 2822 Glenfield Street, Dallas, Texas, was conducted on March 6-9, 2001, by Food and Drug Administration (FDA) investigators from this office. During the inspection of this firm, labels from three flavors of Propel Fitness Water labeled as Purified Water with 6 Vitamins were collected for review and evaluation.

The FDA, after review of your labels for these products, has determined they are misbranded under Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

The product "Propel Fitness Water Purified Water with 6 Vitamins" is misbranded within the meaning of Section 403(a)(1) and 403(i)(1) of the Act because the product's statement of identity, "Purified Water with 6 Vitamins" is misleading. From the name, consumers would not be aware of the true nature of the product, as the product contains other ingredients not mentioned in the name, such as a sweetener, citric acid, flavors, etc.

Please note that above the Nutrition Facts panel a fruit is named on each of your Propel labels. The fruit reference should be accompanied with the term "flavored", as required by 21 CFR 101.22 (i) (1) (i).

This letter is not intended to be an all-inclusive list of deficiencies with your product labeling. It is your responsibility to ensure adherence to each

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requirement of the Act and regulations. You should review all of the labels of your beverage products to assure that they comply with the Act and regulations.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to seizure, and/or obtaining a court injunction against further marketing of your beverage products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Gwendolyn Sue Gilbreath, Compliance Officer, at the above address.

Sincerely,


Michael A. Chappell
Dallas District Director

mac:gsg

cc: Ms. Karen A. Hunter
Counsel

Mr. Thomas J. Dixon
Plant Manager
The Quaker Oats Company
2822 Glenfield St.
Dallas, Texas 75233